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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,480	11/20/2003	Yoshiya Gunji	US-102	9006

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EXAMINER	
ODELL, LINDSAY T	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,480	GUNJI ET AL.	
	Examiner	Art Unit	
	Lindsay Odell	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 6-9* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2-4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06 April 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a first action on the merits (mailed on November 18, 2005), Applicants filed a response and amendment received on February 15, 2005. Said amendment cancelled claims 1 and 5, and amended claims 2-4 and 6-9. Claims 2-4 and 6-9 are pending in this instant Office action.

Election/Restriction

2. Applicant's election of Group I, claims 1-7 in a phone election on October 1, 2004 is acknowledged. Affirmation of this election was not made by Applicant in replying to the Office action mailed on November 18, 2005. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

In an amendment filed on February 15, 2005, claims 8-9, subject to rejoinder with claims 2-4 and 6-8, were withdrawn from consideration. Claims 2-4 and 6-8 are examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2002-336315 filed in Japan on November 20, 2002. No translation has been received; thus, the priority document cannot be used to pre-date any intervening prior art

between the filing date of the instant application and the filing date of the foreign priority documents because said papers are not in English.

Information Disclosure Statement

4. As previously noted, the submitted copy of the referenced document Teizi *et al.* listed on the information disclosure statement (IDS) filed April 6, 2004 was not considered because it was incomplete. A complete copy of the referenced document Teizi *et al.* was received on February 15, 2005, and has been considered as noted by the Examiner's initials on the attached copy of the IDS.

Drawings

5. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Compliance with the Sequence Rules

6. The sequence listing, filed in computer readable form (CRF) and paper copy on April 02, 2004 has been received and entered. As previously noted, the statement submitted on April 02, 2004 that affirms that the content of the sequence listing information in the CRF is identical to the paper copy of the sequence listing, and, where applicable, includes no new matter is unsigned. A signed statement regarding the sameness of the CRF and the paper copy of the sequence listing was received February 15, 2005; however the statement does not affirm that no

new matter is included in the CRF. Therefore, the instant application fails to fully comply with the sequence rules. A signed statement regarding no new matter is required.

Withdrawn Objections to the Specification

7. The previous objection to the specification for the use of the trademarks is withdrawn by virtue of Applicant's amendment.

Withdrawn Objections to the Claims

8. The previous objection to claim 3 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment.

Withdrawn Claim Rejections 35 U.S.C. § 112

9. The previous rejection of claims 1-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "**homologous** protein thereof" (emphasis added) is withdrawn by virtue of Applicant's amendment.

10. The previous rejection of claims 1-4 and 6-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "L-lysine **analogue**" (emphasis added) has been withdrawn by virtue of Applicant's amendment.

11. The previous rejection of claims 1-5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "methanol-assimilating bacterium" and its defining language is withdrawn by virtue of Applicant's amendments and arguments. Regarding the defining language for "methanol-assimilating bacterium", Examiner understands, as a result of Applicant's arguments, that the term "major" in the phrase "major carbon source" means the *predominant* , i.e. "major" means that the carbon source is the predominant source.

12. The previous rejection of claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "at least the glycine residue at position 56" is withdrawn by virtue of Applicant's amendment.

13. The previous rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite because item B is drawn to a DNA that encodes a wild-type LysE protein, but, is dependent on a claim drawn to a DNA encoding a mutant LysE protein, is withdrawn by virtue of Applicant's amendment.

14. The previous rejection of claims 2-4 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "stringent conditions" is withdrawn by virtue of Applicant's amendment.

15. The previous rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendments.

16. The previous rejection of claims 1 and 5 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicant's cancellation of the claims.

Maintained Claim Rejections 35 U.S.C. § 112

17. The previous rejection of claims 2-4 and 6-7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained and amended. Applicants arguments have been fully considered, but are not found persuasive for the following reasons. Applicants have amended the claims to be drawn to the genus of any DNA that encodes a mutant LysE protein of a coryneform bacteria in which the glycine residue at position 56 is replaced with another amino acid residue, and not more than 10 amino acid residues at positions other than the 56th residues are varied, wherein said mutant impart resistance to S-(2aminoethyl-cysteine) in a methylotroph.

Applicants argue that one of ordinary skill in the art would be enabled to make and use the invention as claimed in light of the specification and knowledge in the art concerning the LysE protein. However, Applicants do not provide any specific references in the specification or the art that provide guidance as to "particular residues whose encoding is important within the disclosed sequence so that its mutant LysE-nature is maintained except for amino acid residue glycine 56" (see 35 U.S.C. § 112, first paragraph, enablement rejection for claims 1-7 of the previous Office Action). The Examiner adds that the predictability of making isolated nucleotides that encode polypeptides with less than 100% sequence identity to positions SEQ ID NO: 1 with a mutation at glycine 56, which also maintain the function of imparting resistance to S-(2aminoethyl-cysteine) in a methylotroph, can be increased by comparing the sequences of a genus of known lysE genes to SEQ ID NO:1 and identifying important/conserved residues.

However, the Examiner finds no such comparison in the specification or the art, nor does the Examiner find evidence that a sufficient number of lysE genes are known such that a useful comparison could be performed. Thus, the instant claims are not enabled to the full extent of their scope.

Withdrawn Claim Rejections 35 U.S.C. § 101

18. The previous rejection of claims 1-6 under 35 U.S.C. § 101, made because the claimed inventions were directed to non-statutory subject matter, is withdrawn by virtue of Applicant's amendment.

Withdrawn Claim Rejections - 35 USC § 102

19. The previous rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Vrljic *et al.* (see IDS filed April 6, 2004) as evidenced by Pompejus *et al.* (USPAP 2003/0049804, paragraph [0168]) is withdrawn by virtue of Applicant's cancellation of said claim.

NEW ISSUES

Claim Rejections 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. Claim 2, part B recites the limitation "said" in the phrase "when introduced into **said** methylotroph" (emphasis added). There is insufficient antecedent basis for this limitation in the claim. Clarification is required.

21. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In part B) ii) of claim 2, the claim recites that "amino acid residues at positions other than the 56th residue are substituted, deleted or inserted." It is unclear how to identify the 56th glycine residue in the event that there is a deletion or an insertion that could result in a change in the position of said glycine residue. The Examiner suggests including the phrase ---of SEQ ID NO: 2--- after the phrase "the glycine residue at position 56" in part B) i) of claim 2 in order to clarify what is meant by position 56 in the event of a deletion or insertion. Clarification is required.

Other Art for Comment

22. As previously noted, the following are cited to complete the record:

a) WO 0100843 (Pompejus *et al.*) teaches *Corynebacterium glutamicum* wild-type lysE, which is 100% identical to SEQ ID NO: 1, but not the mutants of the instant claims.

b) EP 1108790 (Nakagawa *et al.*) teaches *Corynebacterium glutamicum* wild-type lysE, which is 100% identical to SEQ ID NO: 1, but not the mutants of the instant claims.

Summary of Pending Issues

23. The following are a summary of the issues pending in the instant application:

a) The Application still does not comply with the sequence rules because a signed statement regarding new matter is missing.
b) Claims 2-4 and 6-7 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
c) Claims 2 and 4 are rejected under 35 U.S.C. § 112, second paragraph.

Conclusion

24. Claims 2-4 and 6-7 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy ms set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1. 136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KATHLEEN KERR, PH.D.
PRIMARY EXAMINER

Lindsay Odell, Ph.D.
May 2, 2005